and specificity) using ANCOVA, and construct validity using exploratory factor analysis with varimax rotation. **RESULTS:** Eighty-five students (2A = 47; 2B = 38) completed the study. Baseline HRQL was not statistically different. The reliability coefficient for the instrument was higher than 80%. ANCOVA showed reasonable responsiveness, i.e., statistically significant differences between Scenario 1–2A and no differences between Scenario 1–2B, as expected. Factor analysis indicated 7 factors; some modification would be needed in two of the items. **CONCLUSION:** Initial validation of an HRQL instrument for multiple chronic conditions indicated good reliability and responsiveness; however minor modifications would be needed to improve construct validity before the instrument is ready for use in a MTM clinic.

PCV75

LINGUISTIC VALIDATION OF THE KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE IN 30 LANGUAGES

Kim J[1], Chevallet L[2], Spertus J[3]

[1]Amgen Inc, Thousand Oaks, CA, USA, [2]Mapi Research Institute, Lyon, Rhone, France, [3]University of Missouri, Kansas City, MO, USA

OBJECTIVES: The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a valid, reliable and sensitive measure through which to quantify heart failure (HF) patients' health status (symptoms, function and quality of life). Prior to its use in an international clinical trial of HF patients, the original 23-item KCCQ needed to be translated into 30 languages/cultures. **METHODS:** The original instrument was developed in US English, with input from Mapi Research Institute on the best terminology to facilitate future translations. To ensure conceptual equivalence and cultural relevance, the translation process was conducted by specialists in each target country across the EU, CEE, and Latin America, using the following standardized methodology: 1) two independent forward translations by professional translators who were native speakers of the target language and fluent in English; 2) comparison and reconciliation of the translations by the specialist in the target country and the translators; 3) backward translation by a native English speaker; 4) comparison of source and backward version with the original KCCQ developer; 5) review by a clinician; 6) comprehension test on 5 HF patients; and 7) international harmonization. **RESULTS:** The translation process revealed challenges where the formulation of the original items made use of specific examples to describe an item concept. Since a literal translation of these specific examples was not always culturally relevant, these specific examples were replaced by generic terms. After completing these changes and international harmonization, all 30 versions were certified by Mapi to be conceptually equivalent to the original questionnaire and culturally relevant for each country. **CONCLUSION:** The KCCQ, translated into 30 languages, can be used as a valid and reliable instrument to evaluate HF patients' health status globally. Harmonization of these versions will facilitate international comparison of results and pooling of data when used in international studies involving quantification of HF patients' health status.

DIABETES—Clinical Outcomes Studies

PDB1

RECENT TRENDS IN OBESITY-RELATED CO-MORBIDITIES AND MEDICAL COSTS IN THE US

Liu G[1], Tian H[2], Le TK[3], Zhao Z[3]

[1]Peking University, Beijing, China, [2]RAND Corporation, Santa Monica, CA, USA, [3]Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: To document the recent dynamic changes in prevalence of obesity and medical comorbidities and costs for the U.S. general population. **METHODS:** This study analyzed data from the 2000 and 2004 Medical Expenditure Panel Survey (MEPS), a nationally representative panel data. Based on Body Mass Index (BMI), weight groups were defined as Underweight (UW, BMI < 18.5), Normal Weight (NW, BMI 18.5–24.9), Overweight (OW, BMI 25–29.9), Obese I (BMI 30–34.9), Obese II (BMI 35–39.9), and Obese III (BMI <= 40). Univariate analyses were conducted to examine changes in obesity prevalence, as well as the trend differentials in demographic and socioeconomic status. Trends in co-morbidities and medical costs were compared among different weight groups across years. All estimates are weighted to be nationally representative. **RESULTS:** The prevalence of obesity increased from 22.5% to 25.9% between year 2000 and 2004 (Obese I: 14.6% vs 16.4%, Obese II: 5.1% vs 6.1%, and Obese III: 2.8% vs 3.4%). Obesity increased more among African-Americans, individuals who had higher education, higher income, and public health insurance. For both years, obesity was consistently associated with the greatest risk of diabetes, high blood pressure, cardiovascular disease, asthma and joint pain ($p > 0.001$). In 2000 dollars, the change in total medical costs was from $3159 in 2000 to $3854 in 2004 for obese groups; $2324 to $3000 for NW; and $2345 to $3088 for OW, all at highly significant level of $p < 0.001$. Obesity related physician office-based costs, ER costs and RX costs were also increased as compared to other groups ($p < 0.001$). **CONCLUSION:** The prevalence of obesity has increased since 2000, resulting in an increase in obesity related comorbidities and medical costs. This study also showed that obesity may be associated with race, socioeconomic status, education, and health insurance.

PDB2

GLYCAEMIC AND WEIGHT EFFECTS OF EXENATIDE FOR DIFFERENT AGE GROUPS

Wintle M[1], Guan X[1], Mac S[1], Brodows R[2], Kim D[1]

[1]Amylin Pharmaceuticals, Inc, San Diego, CA, USA, [2]Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: The incretin mimetic exenatide improves glycaemic control with associated weight reduction in patients with type 2 diabetes (T2DM) treated with metformin (MET), a sulphonylurea (SU), or both. As pharmacokinetics and pharmacodynamics for a given drug can vary with age, we explored exenatide's efficacy and safety for different age groups. **METHODS:** Patients who completed 2 y of exenatide treatment in this interim analysis (N = 283, 63% male, age 57.3 ± 9.7 y; weight 100 ± 19 kg, HbA_{1c} 8.3 ± 1.0%, fasting plasma glucose [FPG] 9.7 ± 2.5 mmol/L, duration of diabetes 8.1 ± 6.1 y, mean ± SD) had statistically significant ($P < 0.05$) mean (±SE) reductions in HbA_{1c} (−1.1 ± 0.1%), FPG (−1.4 ± 0.2 mmol/L), and weight (−4.7 ± 0.3 kg). **RESULTS:** When examined by baseline age (<45 y, n = 26, 45–54 y, n = 91, 55–64 y, n = 97, ≥65 y, n = 69), mean (±SE) reductions in $HbA_{1c>}$ (−1.1 ± 0.2%, −1.0 ± 0.1%, −1.3 ± 0.1%, and −1.2 ± 0.1%, respectively), weight (−3.6 ± 1.0 kg, −4.6 ± 0.7 kg, −4.9 ± 0.6 kg, and −4.9 ± 0.6 kg), and FPG (−1.1 ± 0.4 mmol/L, −1.1 ± 0.3 mmol/L, −1.7 ± 0.3 mmol/L, and −1.5 ± 0.3 mmol/L) were not age dependent. Overall, 54% (N = 283) of eligible patients completed 2 y of exenatide, with withdrawal of consent (15%) and adverse event (9%) the most common reasons for withdrawal. Completion rates varied by age group (35%, 51%, 58%, and 68%), as did the frequency of those withdrawing due to adverse events (4%, 7%, 11%, and 11%) and withdrawal of consent (19%, 18%, 15%, and 8%). Nausea was the most common adverse event for all age groups. Incidence of